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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,467	08/13/2001	Spiridon Spireas	MPCI-0033	6452

7590 07/22/2002

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EXAMINER

NGUYEN, HELEN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,467

Applicant(s)

SPIREAS, SPIRIDON

Examiner

Helen Nguyen

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 5,25,45-52,59 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-24,26-44,53-58,60-66 and 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-44, 53-66, and 68-73, drawn to composition. In addition, Applicants election of the species ethanol as a stabilizer, and corn starch as an adjuvant, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that both composition and process of making claims should be examined together and a search of both Groups would not place an additional burden on the examiner. This is not found persuasive because the record set forth in the previous restriction requirement clearly indicates that the delineated inventions are, in fact, patentably distinct, each from the other, and their different classification would necessitate additional searching.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-73 are pending.

Claims 5, 25, 45-52, 59, and 67 are non-elected.

Claims 1-4, 6-24, 26-44, 53-58, 60-66, and 68-73 are presented for examination.

Priority

The claimed priority of this application to US Provisional Application No. 60/235,349, filed on September 26, 2000, is acknowledged.

Claim rejection- 35 USC § 112

❖ The following is a quotation of the **second paragraph of 35 U.S.C. 112**:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-24, 26-44, 53-58, 60-66, and 68-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 21, 53, 57, 64, 65, 68, and 69, the term “susceptible” is vague. Under what condition?

Claim rejection- 35 USC § 102

❖ The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was

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published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1-4, 6-24, 26-31, 35-44, 53-58, 60-64 are rejected under **35**

U.S.C. 102(e) as being anticipated by Vilkov (US Patent No.

6,294,198 B1).

Vilkov teaches gabapentin processing with ethanol (title, abstract, column 5, lines 35-37), starch (column 6, line 20), and calcium stearate (column 6, line 14). A tablet is specified (abstract).

- As to the claimed properties, the anticipatory compositions must possess these properties because it is the same compositions as that claimed.
- As to the claimed crystalline anhydrous form, the active is well-known in the art as such.

2. Claims 65-66, 68-73 are rejected under **35 U.S.C. 102(e)** as being anticipated by Vilkov (US Patent No. 6,294,198 B1).

Vilkov teaches gabapentin processing with ethanol (title, abstract, column 5, lines 35-37), starch (column 6, line 20), and waxes as a lubricant (column 6, line 12-14). Waxes are equivalent to calcium stearate. A tablet is specified (abstract).

- Gabapentin is well-known to be available as crystallized from ethanol as the base, that is not as a salt.
- As to the claimed properties, the anticipatory composition must possess these properties because it is the same compositions as that claimed.

Claim rejection- 35 USC § 103

- ❖ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-24, 26-44, 53-58, 60-66, and 68-73 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Vilkov (US Patent No. 6,294,198 B1).

Vilkov is discussed above in the first 102.

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- As to the claimed chloride, gabapentin is available as a chloride salt (see Satzinger et al. US Patent No. 4,087,544, column 2, line 10). It is well-known in the art that the salt of an organic compound is more soluble than the organic compound itself. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the chloride salt of gabapentin as the active agent in Vilkov to achieve the beneficial effect of a more soluble active.

Conclusion

Claims 1-4, 6-24, 26-44, 53-58, 60-66, and 68-73 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are

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(703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen
Patent Examiner

July 19, 2002

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500